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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,926	05/04/2001	Markus Graler	101195-45	7274

27387 7590 12/27/2002

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EXAMINER	
BUNNER, BRIDGET E	
ART UNIT	PAPER NUMBER
1647	13

DATE MAILED: 12/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/786,926	GRALER ET AL.	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *2,5-11 and 14-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,12-13, and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-21* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendments of 04 May 2001 (Paper No. 8) and 07 October 2002 (Paper No. 12) have been entered in full. Claims 1-2 are amended and claim 21 is added.

Election/Restrictions

Applicant's election with traverse of Group 1, claims 1, 3-4, and 12-13, drawn to a human EDG6 protein, a DNA sequence encoding EDG6, and use of the EDG6 receptor for therapeutic methods in Paper No. 12 (07 October 2002) is acknowledged. The traversal is on the ground(s) that Groups I (human EDG6 protein and DNA) and II (murine protein and DNA) should be rejoined. Applicant argues that being derived from mouse and human is not a special technical feature under PCT practice. Applicant emphasizes that under PCT practice, a technical feature relates to the elements of the physical embodiments of the inventions. Applicant also argues that the specification and drawings indicate that the proteins of SEQ ID NO: 1 and 4 have virtually identical biological and chemical properties and at least 88% identity of structure. This is not found persuasive. The human protein of SEQ ID NO: 1 and human nucleotide sequence of SEQ ID NO: 2 are structurally unique sequences from the murine protein of SEQ ID NO: 4 and the murine nucleotide sequence of SEQ ID NO: 3, each requiring a unique search of the prior art. For example, the human nucleotide sequence of SEQ ID NO: 2 is a different length and is composed of different nucleic acids compared to the murine nucleotide sequence of SEQ ID NO: 3. Additionally, the human polypeptide of SEQ ID NO: 1 is a different length and is composed of different amino acids as compared to the murine polypeptide sequence of SEQ ID NO: 4. Searching all of the sequences in a single patent application would provide an undue search

burden on the Examiner and the USPTO's resources because of the non-coextensive nature of these searches. Therefore, the Examiner has deemed the murine nucleic acid molecule of SEQ ID NO: 3 and the murine amino acid sequence of SEQ ID NO: 4 an independent invention from the sequences of Group I.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1, 3-4, 12-13, and 21 are under consideration in the instant application.

Sequence Compliance

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). **Specifically, the specification discloses primer sequences at pages 10-12 that are not accompanied by the required reference to the relevant sequence identifiers.** This application fails to comply with the requirements of 37 CFR 1.821 through 1.825. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825).

Drawings

2. The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention. Applicant is required to furnish a drawing under 37 CFR 1.81. No new matter may be introduced in the required drawing.

Specification

3. The abstract of the disclosure is objected to because it is more than 1 paragraph in length. Correction is required. See MPEP § 608.01(b).

4. The disclosure is objected to because of the following informalities:

5. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: "HUMAN G-PROTEIN COUPLED EDG6 RECEPTOR, DNA ENCODING THE RECEPTOR, AND USE OF THE SAME".

Appropriate correction is required.

Information Disclosure Statement

6. The information disclosure statement filed 08 June 2001 (Paper No. 9) fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. It is noted to Applicant that the crossed off reference (a book title) has not been considered because no specific page numbers have been attached.

Claim Objections

7. Claims 1 and 21 are objected to because of the following informalities:

7a. Claims 1 and 21 should recite "SEQ ID NO:" rather than "SEQ ID NO".

7b. Claim 21 recites a non-elected group (SEQ ID NO: 4).

Appropriate correction is required.

Claim Rejections - 35 USC § 101 and § 112, first paragraph

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 3-4, 12-13, and 21 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims read on a product of nature in that the claimed polynucleotide is not "isolated". Amending the claims to read "isolated" would be remedial.

9. Claims 1, 3-4 and 21 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility. Novel biological molecules lack well established utility and must undergo extensive experimentation.

Specifically, claims 1, 3-4, and 21 are directed to a mammalian G-protein coupled receptor EDG6 consisting of SEQ ID NO: 1. The claims also recite a DNA sequence coding the human G-protein coupled receptor EDG6 as well as its fragments, variants and mutations.

The specification asserts that the human G-protein coupled receptor (GPCR) polynucleotide (SEQ ID NO: 2) and polypeptide (SEQ ID NO: 1) of the present invention are involved in forwarding information from the extracellular environment to the inner of the cell through interaction with G-proteins (pg 1, lines 7-14). However, the instant specification does not teach any significance or functional characteristics of the EGD6 GPCR polynucleotide (SEQ ID NO: 2) or polypeptide (SEQ ID NO: 1). The specification also does not disclose any methods or working examples that indicate the polynucleotide and polypeptide of the instant invention are involved in any activity. Since significant further research would be required of the skilled

artisan to determine how the claimed polynucleotide and polypeptide is involved with an activity, the asserted utilities are not substantial. Additionally, G protein-coupled receptors (GPCRs) and signaling molecules are extremely diverse, as evidenced by Ji et al. (J Biol Chem 273(28): 17299-17302, 1998), and each new GPCR/signalling molecule needs to be evaluated empirically to determine the precise role(s) it plays. Since the utility is not presented in mature form and significant further research is required, the utility is not substantial. The specification asserts the following as patentable utilities for the claimed putative EDG6 polynucleotide (SEQ ID NO: 2) and polypeptide (SEQ ID NO: 1):

1) to produce antibodies against the polypeptides (pg 3, lines 22-29; pg 4, lines 1-2)

2) to construct EDG6-deficient mice (pg 4, lines 3-34)

3) to diagnose diseases caused by expression deviating from the norm or by receptor mutation (pg 5, lines 13-16)

4) in gene/protein therapy (pg 5, lines 20-25)

5) in tissue typing (pg 8, lines 12-17; pg 14-15)

Each of these shall be addressed in turn.

1) to produce antibodies against the polypeptides. This asserted utility is credible but not specific or substantial. Antibodies can be made to any polypeptide. However, if the specification discloses nothing specific and substantial about the polypeptide, therefore both polypeptide and its antibodies have no patentable utility. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

2) to construct EDG6-deficient mice. This asserted utility is credible but not specific or substantial. The specification does not disclose diseases associated with a mutated, deleted, or

translocated EDG6 polynucleotide (SEQ ID NO: 2). Significant further experimentation would be required of the skilled artisan to identify such a disease. The specification discloses nothing about what specific tissues and cells are being targeted. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

3) to diagnose diseases caused by expression deviating from the norm or by receptor mutation. This asserted utility is credible but not specific or substantial. Such assays can be performed with any polynucleotide or polypeptide. Further, the specification discloses nothing about the normal levels of expression of the polynucleotide and polypeptide. The altered or abnormal levels of the polynucleotide and polypeptide cannot be determined until a baseline control level is established. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

4) in gene therapy. This asserted utility is credible but not specific or substantial. Such can be performed for any polynucleotide or polypeptide. Further, the specification does not disclose diseases associated with a mutated, deleted, or translocated EDG 6 gene (SEQ ID NO: 2) or protein (SEQ ID NO: 1). Significant further experimentation would be required of the skilled artisan to identify individuals with such a disease and to determine the route of administration of the gene and protein, as well as quantity and duration of treatment. Since this asserted utility is also not presented in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

5) in tissue typing. This asserted utility is credible but not substantial or specific. Such assays can be performed with any polynucleotide. Further, the specification does not disclose

specific DNA sequences for use as markers for RFLP, to prepare primers, or to amplify DNA. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial. Furthermore, the asserted patentable utility of tissue typing for the claimed EDG6 polynucleotide is not substantial because one skilled in the art would not readily use the nucleotide sequences for tissue-typing in a real world sense since the DNA/protein is not specific to one tissue and is not associated with any disease or disorder (see pg 7-8). Furthermore, this asserted utility is not specific because numerous unrelated nucleotide sequences would also show a similar tissue typing pattern. Also, evidence of mere expression in a tissue is not tantamount to a showing of a role in any biological activity.

10. Claims 1, 3-4, and 21 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

11. Furthermore, claims 3 and 13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 3 is directed to a DNA sequence coding the human G-protein coupled receptor EDG6 as well as its fragments, variants, and mutations. Claim 13 recites use of the EDG6 receptor as well as its fragments, variants, and mutations and, if applicable, its binding partners for therapeutic methods and treatments.

The specification of the instant application teaches that the invention is concerned with the use of the EDG6 nucleic acids and EDG6 polypeptides in original, modified, or synthetic form as the initial basis for the development of pharmaceutically relevant substances (pg 4, lines 29-32). The specification at page 5, lines 20-25 disclose that the EDG6 receptor in an original or modified form can be used for therapeutic purposes if a malfunction of the receptor or faulty expression of the EDG6 receptor or its ligand exists. However, the specification does not teach any methods or working examples that indicate the human EDG6 receptor of SEQ ID NO: 1 or the EDG6 polynucleotide of SEQ ID NO: 2 treat any diseases or disorders. The specification of the instant application at page 5 outlines a prophetic example for treating a malfunction of the receptor or faulty expression of the EDG6 receptor or its ligand by utilization of the EDG6 receptor for therapeutic purposes. However, this is not adequate guidance, but is merely an invitation to the artisan to use the current invention as a starting point for further experimentation. Significant experimentation would be required of the skilled artisan to identify individuals or cells with a condition caused by a malfunctioning human EDG6 receptor or faulty EDG6 expression and to determine the route of administration of the protein/gene, as well as quantity and duration of treatment. Such trial and error experimentation is considered undue.

Furthermore, the specification does not teach any variant EDG6 polynucleotide or polypeptide variant, fragment, or mutant other than the full-length polynucleotide of SEQ ID NO: 2 and polypeptide of SEQ ID NO: 1. The specification also does not teach functional or structural characteristics of the EDG6 polynucleotide and polypeptide recited in the claims.

The problem of predicting protein and DNA structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein and

DNA is extremely complex. While it is known that many amino acid substitutions are generally possible in any given protein the positions within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of success are limited. Certain positions in the sequence are critical to the protein's structure/function relationship, e.g. such as various sites or regions directly involved in binding, activity and in providing the correct three-dimensional spatial orientation of binding and active sites. These or other regions may also be critical determinants of antigenicity. These regions can tolerate only relatively conservative substitutions or no substitutions (see Wells, 1990, Biochemistry 29:8509-8517; Ngo et al., 1994, The Protein Folding Problem and Tertiary Structure Prediction, pp. 492-495). However, Applicant has provided little or no guidance beyond the mere presentation of sequence data to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the protein which are tolerant to change (e.g. such as by amino acid substitutions or deletions), and the nature and extent of changes that can be made in these positions. Even if an active or binding site were identified in the specification, they may not be sufficient, as the ordinary artisan would immediately recognize that an active or binding site must assume the proper three-dimensional configuration to be active, which conformation is dependent upon surrounding residues; therefore substitution of non-essential residues can often destroy activity. The art recognizes that function cannot be predicted from structure alone (Bork, 2000, Genome Research 10:398-400; Skolnick et al., 2000, Trends in Biotech. 18(1):34-39, especially p. 36 at Box 2; Doerks et al., 1998, Trends in Genetics 14:248-250; Smith et al., 1997, Nature Biotechnology 15:1222-1223; Brenner, 1999, Trends in Genetics 15:132-133; Bork et al., 1996, Trends in Genetics 12:425-427).

Due to the large quantity of experimentation necessary to identify individuals or cells with a condition caused by a malfunctioning human EDG6 receptor or faulty EDG6 expression, to determine the route of administration of the EDG6 protein/gene, as well as quantity and duration of treatment, and to generate the infinite number of derivatives recited in the claims and possibly screen same for activity, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to all of the above, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure and function, and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

12. Claims 3 and 13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 3 is directed to a DNA sequence coding the human G-protein coupled receptor EDG6 as well as its fragments, variants, and mutations. Claim 13 recites use of the EDG6 receptor as well as its fragments, variants, and mutations and, if applicable, its binding partners for therapeutic methods and treatments.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus.

The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, there is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed EDG6 genus. Additionally, the description of one polynucleotide species (SEQ ID NO: 2) and one polypeptide species (SEQ ID NO: 1) is not adequate written description of an entire genus of functionally equivalent polynucleotides and polypeptides which incorporate all EDG6 polynucleotide and polypeptide variants, fragments, and mutants.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed"* (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116).

With the exception of the sequences referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid

itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only an isolated polynucleotide consisting of the sequence of SEQ ID NO: 2 and an isolated polypeptide consisting of the amino acid sequence of SEQ ID NO: 1, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1, 3-4, 12-13, and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

14. Regarding claims 1, 3-4, 12-13, and 21, the acronym "EDG6" renders the claims vague and indefinite. Abbreviations should be spelled out in all independent claims for clarity.

15. The term "wherein there exists sequence 2" in claim 4 is a relative term which renders the claim indefinite. The term "wherein there exists sequence 2" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of

ordinary skill in the art would not be reasonably apprised of the scope of the invention. Although this phrase is not clear in claim 4, the Examiner has interpreted it to be a referral to the nucleotide sequence of SEQ ID NO: 2. Please note this issue could be overcome by amending claim 4 to recite "The DNA according to claim 3, wherein the DNA consists of the nucleic acids of SEQ ID NO: 2".

16. Claim 12 is rejected as being indefinite because it cannot be determined from the claim language what products are encompassed in the test kit for the detection of the EDG6 receptor on the basis of nucleic acid diagnostics. It is noted that the Examiner has interpreted this claim to encompass nucleic acid products, such as probes and primers.

17. Claim 13 provides for the use of the EDG6 receptor as well as its fragments, variants, and mutations, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 13 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 1, 12, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Graler et al. (Genomics 53(2): 164-169, 1998). It is noted to Applicant that since the claimed human EDG6 polynucleotide of SEQ ID NO: 2 and the polypeptide of SEQ ID NO: 1 have no utility under 35 U.S.C. §101, first paragraph, the effective filing date of the instant application is May 4, 2001.

Graler et al. teaches the G-protein coupled receptor EDG6 having the amino acid sequence of SEQ ID NO: 1 of the instant application. (See sequence alignment attached to this Office Action as Appendix A; see amino acids 1-184 of SEQ ID NO: 1 of the instant application; see also amino acids 1-184 of hEDG6 in Figure 1 of Graler et al.)

19. Claims 3-4 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Graler et al. (Accession No. AJ000479, GenEmbl, 17 Nov 1998). It is noted to Applicant that since the claimed human EDG6 polynucleotide of SEQ ID NO: 2 and the polypeptide of SEQ ID NO: 1 have no utility under 35 U.S.C. §101, first paragraph, the effective filing date of the instant application is May 4, 2001.

Graler et al. teaches the DNA sequence coding the human G-protein coupled receptor EDG6. Graler et al. also discloses the nucleic acid sequence of SEQ ID NO: 2 of the instant application. (See sequence alignment attached to this Office Action as Appendix B; see nucleotides 1-1155 of the instant application; see also nucleotides 23-1177 of Graler et al.)

Conclusion

No claims are allowable

The art made of record and not relied upon is considered pertinent to applicant's disclosure:

Munroe et al. U.S. Patent No. 6,020,158

Munroe et al. U.S. Published Application No. 20020142375

Yamazaki et al. Biochem Biophys Res Commun. 268(2):583-9, 2000.

Graler et al. Curr Top Microbiol Immunol. 246:131-6, 1999.

Lynch et al. Trends Pharmacol Sci. 20(12):473-5, 1999.

Van Brocklyn et al. Blood 95(8):2624-9, 2000.

Graler et al. Accession No. AJ000479, GenEmbl database, 17 Nov 1998.

Gupta et al. Accession No. AAX59366, Geneseq database, 20 Sept 1999.

Gupta et al. Accession No. AAY06411, Geneseq database, 20 Sept 1999.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 8:30-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 872-9305.

Gary L. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

BEB
Art Unit 1647
December 23, 2002

Appendix A

ALIGNMENTS

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RESULT 1
O95977
ID   O95977       PRELIMINARY;      PRT:   384 AA.
AC   O95977;
DT   01-MAY-1999 (TrEMBLrel. 10, Created)
DT   01-MAY-1999 (TrEMBLrel. 10, Last sequence update)
DT   01-MAR-2002 (TrEMBLrel. 20, Last annotation update)
DE   Putative G-protein coupled receptor, EDG6 precursor (Hypothetical 41.6
DE   kDa protein).
GN   EDG6.
OS   Homo sapiens (Human).
OC   Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
OC   Mammalia; Eutheria; Primates; Catarrhini; Hominidae; Homo.
OX   NCBI_TaxID=9606;
RN   [1]
RP   SEQUENCE FROM N.A.
RX   MEDLINE=99009331; PubMed=9790765;
RA   Graeler M.H., Bernhardt G., Lipp M.;
RT   "EDG6, a novel G protein-coupled receptor related to receptors for
RT   bioactive lysophosphopilpids, is specifically expressed in lymphoid
RT   tissue.";
RL   Genomics 53:164-169(1998).
RN   [2]
RP   SEQUENCE FROM N.A.
RC   TISSUE=BLOOD;
RA   Strausberg R.;
RL   Submitted (OCT-2001) to the EMBL/GenBank/DDBJ databases.
DR   EMBL; AJ000479; CAA04118.1; -.
DR   EMBL; BC014970; AAH14970.1; -.
DR   InterPro; IPR004064; EDG6receptor.
DR   InterPro; IPR000276; GPCR_Rhodpsn.
DR   InterPro; IPR004061; S1Preceptor.
DR   Pfam; PF00001; 7tm_1; 1.
DR   PRINTS; PR01526; EDG6RECEPTOR.
DR   PRINTS; PR00237; GPCRRHODOPSN.
DR   PRINTS; PR01523; S1PRECEPTOR.
DR   PROSITE; PS50262; G_PROTEIN_RECEP_F1_2; 1.
KW   G-protein coupled receptor; Hypothetical protein; Receptor; Signal.
FT   SIGNAL       1     22       POTENTIAL.
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Mon Dec 9 12:35:27 2002 **us-09-786**

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SQ   SEQUENCE   384 AA;  41623 MW;  369A7BC56AB46A47 CRC64;

  Query Match          100.0%;  Score 1966;  DB 4;  Length 384;
  Best Local Similarity  100.0%;  Pred. No. 4.7e-151;
  Matches  384;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy       1 MNATGTPVAPESCQQLAAGGHSRLIVLHYNHSGRLAGRGGPEDGGLGALRGLSVAASCLV 60
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Db       1 MNATGTPVAPESCQQLAAGGHSRLIVLHYNHSGRLAGRGGPEDGGLGALRGLSVAASCLV 60

Qy      61 VLENLLVLAAITSHMRSRRWVYYCLVNITLSDLLTGAAYLANVLLSGARTFRLAPAQWFL 120
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
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Qy     121 REGLLFTALAASTFSLLFTAGERFATMVRPVAESGATKTSRVYGFIGLCWLLAALLGMLP 180
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
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Qy     181 LLGWNCLCAFDRCSSLLPLYSKRYILFCLVIFAGVLATIMGLYGAIFRLVQASGQKAPRP 240
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
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Qy     241 AARRKARRLLKTVLMILLAFLVCWGPLFGLLLADVFGSNLWAQEYLRGMDWILALAVLNS 300
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
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Qy     301 AVNPIIYSFRSREVCRAVLSFLCCGCLRLGMRGPGDCLARAVEAHSGASTTDSSLRPRDS 360
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Db     301 AVNPIIYSFRSREVCRAVLSFLCCGCLRLGMRGPGDCLARAVEAHSGASTTDSSLRPRDS 360

Qy     361 FRGSRSLSFRMREPLSSISSVRSI 384
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Db     361 FRGSRSLSFRMREPLSSISSVRSI 384


RESULT 2
O9ZOL1
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LOCUS       HSEDG4                  1566 bp    mRNA    linear   PRI 17-NOV-1998
DEFINITION  Homo sapiens mRNA for putative G-protein coupled receptor, EDG6.
ACCESSION   AJ000479
VERSION     AJ000479.1  GI:3805931
KEYWORDS    edg6 gene; G-protein coupled receptor.
SOURCE      Homo sapiens.
  ORGANISM  Homo sapiens
            Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
            Mammalia; Eutheria; Primates; Catarrhini; Hominidae; Homo.
REFERENCE   1  (bases 1 to 1566)
  AUTHORS   Graeler,M.H.
  TITLE     Direct Submission
  JOURNAL   Submitted (16-JUL-1997) Graeler M.H., Molekulare Tumorgenetik,
REFERENCE   2  (bases 1 to 1566)
  AUTHORS   Graler,M.H., Bernhardt,G. and Lipp,M.
  TITLE     EDG6, a novel G-protein-coupled receptor related to receptors for
            bioactive lysophospholipids, is specifically expressed in lymphoid
            tissue
  JOURNAL   Genomics 53 (2), 164-169 (1998)
  MEDLINE   99009331
   PUBMED   9790765
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                     and GM-CSF"
     gene            23..1177
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                     RVYGFIGLCWLLAALLGMLPLLGWNCLCAPDRCSSLLPLYSKRYILFCLVIPAGVLAT
                     IMGLYGAIFRLVQASGQKAPRPAARRKARRLLKTVLMILLAFLVCWGPLFGLLLADVF
                     GSNLWAQGRTLRGMDWILALNSAVNPIIYSFRSREVCRAVLSFLCCGLLGMRGP
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                     /gene="edg6"
BASE COUNT      211 a    536 c    523 g    296 t
ORIGIN

  Query Match           100.0%;  Score 1155;  DB 9;  Length 1566;
  Best Local Similarity  100.0%;  Pred. No. 2.4e-140;
  Matches 1155;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy       1 ATGAACGCCACGGGGACCCCGGTGCCCCCGAGTCCTGCCAACAGCTGGCGGCCGGCGGG 60
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      23 ATGAACGCCACGGGGACCCCGGTGGCCCCGAGTCCTGCCAACAGCTGGCGGCCGGCGGG 82

Qy      61 CACAGCCGGCTCATTGTTCTGCACTACAACCACTCGGGCCGGCTGGCCGGGCGCGGGGGG 120
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      83 CACAGCCGGCTCATTGTTCTGCACTACAACCACTCGGGCCGGCTGGCCGGGCGCGGGGGG 142

Qy     121 CCGGAGGATGGCGGCCTGGGGGCCCTGCGGGGGCTGTCGGTGGCCGCCAGCTGCCTGGTG 180
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     143 CCGGAGGATGGCGGCCTGGGGGCCCTGCGGGGGCTGTCGGTGGCCGCCAGCTGCCTGGTG 202

Qy     181 GTGCTGGAGAACTTGCTGGTGCTGGCGGCCATCACCAGCCACATGCGGTCGCGACGCTGG 240
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Db     203 GTGCTGGAGAACTTGCTGGTGCTGGCGGCCATCACCAGCCACATGCGGTCGCGACGCTGG 262

Qy     241 GTCTACTATTGCCTGGTGAACATCACGCTGAGTGACCTGCTCACGGGCGCGGCCTACCTG 300
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Qy     301 GCCAACGTGCTGCTGTCGGGGGCCCGCACCTTCCGTCTGGCGCCCGCCCAGTGGTTCCTA 360
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Qy     361 CGGGAGGGCCTGCTCTTCACCGCCCTGGCCGGCTCCACCTTCAGCCTGCTCTTCACTGCA 420
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Db     383 CGGGAGGGCCTGCTCTTCACCGCCCTGGCCGGCTCCACCTTCAGCCTGCTCTTCACTGCA 442

Qy     421 GGGGAGCGCTTTGCCACCATGGTGCGGCCGGTGGCCGAGAGCGGGGCCACCAAGACCAGC 480
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Qy     481 CGCGTCTACGGCTTCATCGGCCTCTGCTGGCTGCTGGCCGCGCTGCTGGGGATGCTGCCT 540
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Qy     541 TTGCTGGGCTGGAACTGCCTGTGCGCCTTTGACCGCTGCTCCAGCCTTCTGCCCCTCTAC 600
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Qy     601 TCCAAGCGCTACATCCTCTTCTGCCTGGTGATCTTCGCCGGCGGTCCTGGCCACCATCATG 660
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Qy     661 GGCCTCTATGGGGCCATCTTCCGCCTGGTGCAGGCCAGCGGGCAGAAGGCCCCACGCCCA 720
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Db     683 GGCCTCTATGGGGCCATCTTCCGCCTGGTGCAGGCCAGCGGGCAGAAGGCCCCACGCCCA 742

Qy     721 GCGGCCCGCCGCAAGGCCCGCCGCCTGCTGAAGACGGTGCTGATGATCCTGCTGGCCTTC 780
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Qy     781 CTGGTGTGCTGGGGCCCACTCTTCGGGCTGCTGCTGGCCGACGTCTTTGGCTCCAACCTC 840
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     803 CTGGTGTGCTGGGGCCCACTCTTCGGGCTGCTGCTGGCCGACGTCTTTGGCTCCAACCTC 862

Qy     841 TGGGCCCAGGAGTACCTGCGGGGCATGGACTGGACTGGATCCTGGCCCTGGCCGTCCTCAC 900
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     863 TGGGCCCAGGAGTACCTGCGGGGCATGGACTGGACTGGATCCTGGCCCTGGCCGTCCTCAC 922

Qy     901 GCGGTCAACCCCATCATCTACTCCTTCCGCAGCAGGGAGGTGTGCAGACGCGTGCTCAGC 960
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Db     923 GCGGTCAACCCCATCATCTACTCCTTCCGCAGCAGGGAGGTGTGCAGACGCGTGCTCAGC 982

Qy     961 TTCCTCTGCTGCGGGGTGTCTCCGGCTGGGCATGCGAGGGCCCGGGGACTGCCTGGCCCGG 1020
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Db     983 TTCCTCTGCTGCGGGTGTCTCCGGCTGGGCATGCGAGGGCCCGGGGACTGCCTGGCCCGG 1042

Qy    1021 GCCGTCGAGGCTCACTCCGGAGCTTCCACCACCGACAGCTCTCTGAGGCCAAGGGACAGC 1080
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Db    1103 TTTCGCGGCTCCGCTCGCTCAGCTTTCGGATGCGGGAGCCCCTGTCCAGCATCTCCAGC 1162

Qy    1141 GTGCGGAGCATCTGA 1155
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Db    1163 GTGCGGAGCATCTGA 1177
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